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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/367,496	11/24/99	AGUERA	P06473US0/TP

EXAMINER	
RAWLINGS, S	
ART UNIT	**PAPER NUMBER**
1642	6

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HM22/0213

DATE MAILED: 02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/367,496	AGUERA ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Restriction Election facsimile sheet* .

DETAILED ACTION

1. Claims 1-19 are pending in the application and are subject to restriction/election.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Groups 1-4. Claims 1-7, 9, 10, and 14-17, drawn to a purified polypeptide, derivative, or fragment thereof comprising an

amino acid sequence set forth in either SEQ ID NO: 2, 4, 6, or 8, respectively, a composition comprising said polypeptide, an isolated nucleic acid molecule comprising the polynucleotide sequence set forth in either SEQ ID NO: 1, 3, 5, or 7, respectively, encoding said amino acid sequence, a vector containing said molecule, and a host cell transfected by said vector, the use of said polypeptide, derivative, or fragment thereof in detecting the presence of anti-CV2 antibodies in a sample, a method of diagnosis comprising contacting a sample with said polypeptide, derivative, or fragment thereof, a kit comprising said polypeptide, a pharmaceutical composition comprising said polypeptide, derivative, or fragment thereof, a pharmaceutical composition comprising a nucleic acid molecule encoding a ULIP or an antisense sequence comprising a sequence that hybridizes specifically to said molecule, classified in class 530, subclass 350, class 424, subclass 9.1, class 435, subclass 320.1, class 435, subclass 325, and class 536, subclasses 23.1 and 24.5.

Note: Applicant is required to identify and elect a single sequence (SEQ ID NO: 2, 4, 6, or 8) to which the claims are to be drawn for examination.

Groups 5-8. Claim 8, 16, and 17, in so far as claims 16 and 17 are drawn to an antibody, drawn to an antibody fragments, and

immunoconjugates thereof obtained from a polypeptide comprising the amino acid sequence set forth in either SEQ ID NO: 2, 4, 6, or 8, respectively, classified in class 530, subclass 387.1 and subclass 391.1.

Note: Applicant is required to identify and elect a single sequence (SEQ ID NO: 2, 4, 6, or 8) to which the claims are to be drawn for examination.

Groups 9-12. Claim 11, in so far as it is drawn to the use of an antibody, fragments, and immunoconjugates thereof obtained from a polypeptide comprising the amino acid sequence set forth in either SEQ ID NO: 2, 4, 6, or 8, respectively, to purify said polypeptide, classified in class 530, subclass 413.

Note: Applicant is required to identify and elect a single sequence (SEQ ID NO: 2, 4, 6, or 8) to which the claims are to be drawn for examination.

Group 13. Claim 11, in so far as it is drawn to detection, and claims 12 and 13, drawn to the use of an anti-ULIP antibody to make a diagnosis, classified in class 435, subclass 7.1.

Group 14. Claims 16-17, drawn to a pharmaceutical composition comprising an anti-ULIP antibody and the use of said antibody to make a medicament, classified in class 435, subclasses 7.1.

Groups 15-18. Claim 18, as drawn to the use of one of the following agents: (a) a ULIP, ULIP fragment, or derivative thereof, (b) a nucleic acid molecule encoding a ULIP or ULIP fragment, (c) an antisense nucleic acid molecule capable of hybridizing to a polypeptide sequence encoding a ULIP, or (d) an anti-ULIP antibody, respectively, in making a medicament, classified in class 424, subclass 130.1.

Note: Applicant is required to identify and elect a single agent (a, b, c, or d) to which the claims are to be drawn for examination.

Groups 19-22. Claim 19, drawn to a method for treatment of a neurodegenerative illness comprising the administration to a subject of a therapeutically efficacious quantity of one of the following agents: (a) a ULIP, ULIP fragment, or derivative thereof, (b) a nucleic acid molecule encoding a ULIP or ULIP fragment, (c) an antisense nucleic acid molecule capable of hybridizing to a polypeptide sequence encoding a ULIP, or (d) an anti-ULIP antibody, respectively, classified in class 424, subclass 9.2.

Note: Applicant is required to identify and elect a single agent (a, b, c, or d) to which the claims are to be drawn for examination.

Groups 23-26. Claim 19, drawn to a method for treatment of a neoplasm comprising the administration to a subject of a therapeutically efficacious quantity of one of the following agents: (a) a ULIP, ULIP fragment, or derivative thereof, (b) a nucleic acid molecule encoding a ULIP or ULIP fragment, (c) an antisense nucleic acid molecule capable of hybridizing to a polypeptide sequence encoding a ULIP, or (d) an anti-ULIP antibody, respectively, classified in class 424, subclass 9.2.

Note: Applicant is required to identify and elect a single agent (a, b, c, or d) to which the claims are to be drawn for examination.

3. The inventions listed as Groups 1-26 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Groups 1-4 are drawn to different nucleic acid molecules encoding different polypeptides and a method of using said polypeptides because each polypeptide identified in the claims comprises a distinct amino acid sequence set forth in either SEQ ID NO: 2, 4, 6, or 8 and is encoded by a

distinct polynucleotide sequence set forth in either SEQ ID NO: 1, 3, 5, or 7, respectively.

Groups 1-4 do not share a common technical feature with Groups 5-26 and PCT Rules 13.1 and 13.2 do not provide for multiple products and methods.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Groups 14-23 are further subject to an election of a single disclosed species of generic invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 12, 16, 18, and 19 are generic to a plurality of disclosed patentably distinct species comprising the following proteins of the ULIP family (a) the polypeptide having the amino acid sequence set forth in SEQ ID NO:2, which is encoded by the polynucleotide sequence set forth in SEQ ID NO:1, (b) the polypeptide having the amino acid sequence set forth

in SEQ ID NO:4, which is encoded by the polynucleotide sequence set forth in SEQ ID NO:3, (c) the polypeptide having the amino acid sequence set forth in SEQ ID NO:6, which is encoded by the polynucleotide sequence set forth in SEQ ID NO:5, and (d) the polypeptide having the amino acid sequence set forth in SEQ ID NO:8 and designated POP-66, which is encoded by the polynucleotide sequence set forth in SEQ ID NO:7.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the different family ULIP family members has distinct chemical and biological properties.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as

provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LON A. WORTMAN
PRIMARY EXAMINER

Stephen L. Rawlings, Ph.D.

Art Unit 1642

Signature on p. 9

slr

February 8, 2001

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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